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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,745	01/16/2001	Gunter Schmidt	PM-0276612	7328
909	7590	08/11/2004		
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102				
			EXAMINER LEWIS, PATRICK T	
			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,745

Applicant(s)

SCHMIDT ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Response dated April 1, 2004

1. In the Response filed April 1, 2004, claims 2-24 were amended; claims 25-30 were canceled; and claims 31-35 were added.
2. Claims 1-24 and 31-35 are pending. An action on the merits of claims 1-24 and 31-35 is contained herein below.
3. The objection to claims 5-30 has been rendered moot in view of applicant's amendment filed April 1, 2004.
4. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement, is maintained for the reasons of record as set forth in the Office Action dated October 1, 2003.
5. The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicant's arguments filed April 1, 2004.
6. The rejection of claims 1-4 under 35 U.S.C. 102(b) has been withdrawn in view of applicant's arguments filed April 1, 2004.

Objections/Rejections of Record Set Forth in Office Action

Dated October 1, 2003

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974). The essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

The instant specification is drawn to a compound of formula (I) wherein M comprises a mass marker, N comprises a nucleic acid, and wherein R¹ and R² are each independently selected from a hydrogen atom, a substituted or unsubstituted alkyl group, and a substituted or unsubstituted aryl group. Presently, the examples in the instant specification are limited to the preparation of a mass labeled compound FT23 and mass spectrometry analysis of FT23. Applicants do not provide an adequate written description which provides guidance for the preparation of compounds of formula (I) as instantly claimed. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in

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the art how to make the compound. The process is considered to be incomplete wherein applicant does not set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400. The factors include: 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art, and 7) the breadth of the claims. In the instant case no guidance is provided for preparing the instantly claimed compounds. No working examples are provided (for synthesis of instantly claimed compounds). Indeed with the very limited disclosure provided by applicant, it would require undue experimentation by one of ordinary skill in the art to make the instantly claimed compounds of formula (I).

9. Applicant's arguments filed April 1, 2004 have been fully considered but they are not persuasive. Applicant argues: 1) the specification provides specific examples of the four constituent groups bound to a central silicon atom; 2) the constituent groups of the claimed compounds are common groups in organic chemistry and their properties are well understood by persons skilled in the field to enable them to generate compounds of the general formula (I); 3) understanding that the substituents of N and/or M must be better leaving groups than R1 and R2 is well within the abilities of those with ordinary skill in the art and would not require undue experimentation; and 4) the example demonstrates the

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fact that the reaction mechanism actually works. The examiner respectfully disagrees with applicant's assessment.

While the specification sets forth examples of the four constituent groups, no guidance is provided as to how to attach the constituent groups (R1, R2, N, and M) to the core silicon atom. The disclosure fails to set forth appropriate starting materials for forming the instantly claimed compounds of formula (I). No guidance has been provided as to the order in which the constituent groups are attached to the core silicon atom. The disclosure provides no guidance as to the reaction conditions necessary to effectuate attachment of said constituent groups to the core silicon atom. Since the invention requires that either N or M cleaves from the Si atom in preference to R1 and R2, the starting silicon-containing compound, the order of attachment of constituent groups, and reaction conditions required for said attachments are of critical importance. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. The process is considered to be incomplete wherein applicant does not set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms. No examples of compounds of formula (I) are provided. The only example provided in the disclosure is the synthesis and mass spectrometry analysis of compound FT23; however, the example fails to provide any guidance as to how the attachment of the constituent groups are attached to the core silicon atom. Furthermore, not only does compound FT23 not contain a nucleic acid, the poly-ether mass marker and the nucleic base-containing moiety are not attached through the

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central silicon atom. Indeed with the very limited disclosure provided by applicant, it would require undue experimentation by one of ordinary skill in the art to make the instantly claimed compounds of formula (I).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 5-24 and 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974). The essential novelty, the essence of the invention, must be describe in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

The instant specification is drawn to a compound of formula (I) wherein M comprises a mass marker, N comprises a nucleic acid, and wherein R¹ and R² are each independently selected from a hydrogen atom, a substituted or

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unsubstituted alkyl group, and a substituted or unsubstituted aryl group. The specification is further drawn to a method of characterizing an analyte employing a compound of formula (I). Presently, the examples in the instant specification are limited to the preparation of a mass labeled compound FT23 and mass spectrometry analysis of FT23. Applicants do not provide an adequate written description which provides guidance for the preparation of compounds of formula (I) as instantly claimed. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. The process is considered to be incomplete wherein applicant does not set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms (e.g. all moieties "substituted" wherein the identity of the substituent intended to effectuate said substitution are not set forth in any synthetic procedural steps).

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400. The factors include: 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the

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state of the prior art, 6) the predictability of the art, and 7) the breadth of the claims.

In the instant case no guidance is provided for preparing the instantly claimed compounds. No working examples are provided (for synthesis of instantly claimed compounds). The disclosure fails to set forth appropriate starting materials for forming the instantly claimed compounds of formula (I). No guidance has been provided as to the order in which the constituent groups are attached to the core silicon atom. The disclosure provides no guidance as to the reaction conditions necessary to effectuate attachment of said constituent groups to the core silicon atom. Since the invention requires that either N or M cleaves from the Si atom in preference to R1 and R2, the starting silicon-containing compound, the order of attachment of constituent groups, and reaction conditions required for said attachments are of critical importance. No examples of compounds of formula (I) are provided. The only example provided in the disclosure is the synthesis and mass spectrometry analysis of compound FT23; however, the example fails to provide any guidance as to how the attachment of the constituent groups are attached to the core silicon atom. Furthermore, not only does compound FT23 not contain a nucleic acid, the poly-ether mass marker and the nucleic base-containing moiety are not attached through the central silicon atom. Indeed with the very limited disclosure provided by applicant, it would require undue experimentation by one of ordinary skill in the art to make the instantly claimed compounds of formula (I).

Conclusion

12. Claims 1-24 and 31-35 are pending. Claims 1-24 and 31-35 are rejected.

No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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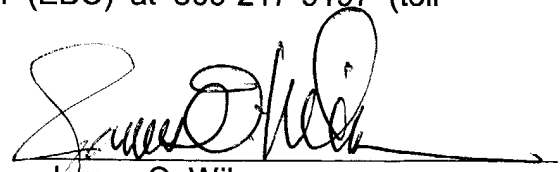
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
August 5, 2004